RECOMBINANT DNA TECHNOLOGY and INFECTIOUS BIOLOGICAL AGENT REGULATIONS
AMHERST BOARD OF HEALTH

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Section 1. Purpose and Scope

The Amherst Board of Health is aware that the use of biohazards, including rDNA, other infectious agents and biologically active agents such as toxins, venoms, and allergens can pose health threats to Amherst residents. Therefore, acting under authority conferred by M.G.L. c .111, section 31 & c.111, section 21 the Amherst Board of Health enacts the following regulation, governing the use of biohazards and rDNA in the Town of Amherst. This regulation applies to all institutions in the Town of Amherst which conduct research involving the use of rDNA or infectious biological agents or toxins. Institutions owned or operated either by the Federal Government or by the Commonwealth such as the University of Massachusetts are excluded from these regulations.

Section 2. Definitions

a) Board of Health - Refers to the Amherst Board of Health or its agent.

b) CDC – Centers for Disease Control and Prevention

c) "DNA" - deoxyribonucleic acid

d) "Recombinant DNA" (RDNA) or "Recombinant DNA molecules"

(1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or

(2) DNA molecules which result from the replication of a molecule described in (1) above.

e) NIH Guidelines" - "Guidelines for Research involving Recombinant DNA Molecules" promulgated by the National Institute of Health (NIH) of the United States Department of Health and Human Services. The most current available version of the guidelines will be used.

f) Infectious biological agent or toxin

(1) Infectious biological agent is defined as any microorganism or infectious substance, or any naturally occurring or bioengineered or synthesized component of any such microorganism or infectious substance capable of causing death, disease or other biological adverse affect in a human, animal, plant or other living organism and/or is deleterious to the environment.

(2) A biological toxin is defined as a harmful substance used in research produced by certain bacteria, fungi, protozoa, plants, reptiles, amphibians, fish, echinoderma, mollusks or insects that can disrupt normal cellular functions and cause illness or death.

(3) Four biosafety levels have been defined by NIH which specify administrative procedures, safety equipment, and facilities for work with biological agent or toxins. Research with biological agents and toxins is assigned to a biosafety level based on the pathogenicity and transmission route of the particular agent or toxin used.

(a) Biosafety Level 1 (BSL-1) is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment.

(b) Biosafety Level 2 (BSL-2) builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment.

(c) Biosafety Level 3 (BSL-3) is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure.

(d) Biosafety Level 4 (BSL-4) is required for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission.

g) Biosafety in Microbiological and Biomedical Laboratories "BMBL" Guidelines. *MGL Ch.44 Sec.53G*. US Department of Health and Human Services, CDC and NIH. The most current edition and any subsequent amendments by NIH or the CDC.

h) "Institution" - any single individual, group of individuals, partnership, association, organization, corporation, educational institution, research institution, or medical facility that conducts research involving either rDNA or infectious biological agents or toxins, excluding any institution owned by either the Federal Government or by the Commonwealth, including but not limited to the University of Massachusetts.

Section 3. Restrictions

rDNA use classified by NIH and BMBL guidelines as requiring biosafety level 4 (BSL-4) level of containment or higher shall be prohibited in the Town of Amherst.

Section 4. Regulations

All Research uses of rDNA and infectious biological agents or toxins by institutions in the Town of Amherst shall be undertaken only in conformity with current and applicable NIH and BMBL guidelines as promulgated in the Federal Register and as may be amended from time to time by the NIH/CDC or by any successor agency. Copies are on file in the Amherst Health Department.

Section 5. Administrative Requirements

Each institution in the Town of Amherst that does research with biological agents or toxins must complete a biological agent registration form. In addition, institutions that experiment with or use rDNA technology or infectious biological agents or toxins at BSL-2 or above shall also comply with the administrative practices set forth in the NIH and BMBL guidelines, including but not limited to the following:

a) Establishment of an Institutional Biosafety Committee (IBC) with at least five members, of whom at least two but not less than 20% shall not be affiliated with the institution and shall represent the interests of the community with respect to health and the protection of the environment. In addition:

(1) The IBC shall contain at least one representative from the institution's biotechnology staff.

(2) The non-affiliated representatives on the IBC shall be nominated by the institution with notice to and approval by the Board of Health.

(3) The non-affiliated representatives on the IBC shall be residents in the Town of Amherst.

(4) The non-affiliated representatives on the IBC shall be bound by the same rules prohibiting use and disclosure of proprietary information and trade secrets as any employee of the institution, and a copy of the institution's rules governing the use and disclosure of such proprietary information shall be given to each non-affiliated representative, the receipt thereof to be acknowledged in writing.

(5) The IBC shall establish a set of rules and administrative procedures governing its operation in accordance with the NIH guidelines, the BMBL and these regulations.
(6) The IBC shall conduct an annual formal documented risk analysis for each institution's programs that utilize rDNA or infectious biological agents or toxins. The results of the risk assessment shall be forwarded to the Board of Health.
(7) The IBC shall meet at least twice annually.
(8) Minutes of all IBC meetings shall be forwarded *within 30 days* to the Board of Health, exclusive of proprietary information.
(9) In the event that the NIH and/or BMBL shall discontinue or abolish their guidelines, those guidelines in effect at the time of such discontinuance shall remain in effect in Amherst until further action by the Board of Health.

b) Preparation of a Health and Safety Manual for all its employees which contains all procedures relevant to the use of rDNA and biological agents or toxins at all levels of containment in use at the institution, and submission of a copy of said manual to the Board of Health.

c) Establishment of a training program of safeguards and procedures for personnel using rDNA or infectious biological agents or toxins.

d) If the institution is engaged in rDNA or BSL-3 biological agents or toxins research at the BSL-3 containment level (as defined in the NIH/CDC standards), the appointment of a Biological Safety Officer who shall be a member of the IBC is mandatory.

e) If the institution is engaged in rDNA or infectious biological agent or toxin research on a "large scale" (as defined by the NIH Large Scale Recommendations), compliance with all additional administrative requirements contained in the NIH Large Scale Recommendations is required.

Section 6. Registration, Permits, Costs and Inspections

a) Registrations

(1) All institutions wishing to conduct research employing rDNA technology or other biohazardous materials must register with the Amherst Board of Health.
(2) The cost for such registration will be $150, annually.
(3) The registration fee will cover administration costs and costs of employing consultants with the expertise necessary to review the application for registration.

b) Permits

(1) Initial special permits from the Amherst Board of Health will be required for research employing rDNA technology or other Biohazardous materials if such agents are considered to be BSL-2 or higher. The cost of the permit shall be commensurate with the cost incurred by the Amherst Board of Health, and will include administration costs and costs of employing consultants with the necessary expertise to review the protocols and procedures describing the research and risk mitigation plans. The costs associated with permitting will not exceed $4,000.

a) Such permit may only be issued after
(1) a comprehensive review of the proposed project(s) by a certified health

expert selected and hired by the Board of Health and,

(2) certification that the institution is in compliance with these regulations and the NIH and BMBL guidelines.

b) Any institution aggrieved by a final decision to deny or grant a permit may seek relief in any court of competent jurisdiction, as provided by the laws of this Commonwealth.

c) The Board of Health shall inspect at least annually, and without prior notice, each institution holding such a permit to ensure compliance with the provisions of these regulations and the NIH and BMBL guidelines.

d) The Board of Health may require from an institution such information and data as necessary to ensure compliance with these regulations.

e) Once a permit has been issued it may be revoked by the Board of Health upon a determination, subject to judicial review, after due notice and hearing, that the institution involved has materially failed to comply with these regulations, the permit agreements, or the NIH/BMBL guidelines, not withstanding reasonable notice and opportunity to correct such failure to comply.

(2) Annual Review

Re-permitting will be required only in the event of substantial changes to the research protocol or a change to the BSL. This will be determined on the basis of the annual registration paperwork. If re-permitting is required, costs will be determined as described above.

Section 7. Environmental Surveillance Programs

All institutions employing rDNA technology or research using infectious biological agents or toxins within the Town of Amherst shall provide appropriate medical and environmental surveillance programs in accordance with the NIH and BMBL guidelines.

a) The environmental surveillance program shall include a plan for the deactivation of biological waste and verification of decontamination processes to ensure that recombinant organisms or infectious biological agents and toxins will not be released into the environment.

b) The environmental surveillance program shall include training of representatives or consultants of the Town of Amherst Board of Health, the Amherst Fire Department, and the Amherst Police Department, in the procedures to be used in the event of an emergency.

c) Any release into the environment of recombinant organisms or infectious biological agents or toxins shall require immediate notification to the Board of Health. In addition, reports shall be made within 24 hours by the institution, first by phone and then confirmed in writing.

Section 8. Penalties

Any institution which violates any provision of these regulations shall be punished by a fine up to $200 per day for each violation. A reasonable notice period of the finding of a violation will be

given to the institution by the enforcing authority to allow for immediate correction of the problem prior to the charging of the fine.

Section 9. Enforcement
Enforcement of these regulations shall be the responsibility of the Board of Health or its designated agent.

Section 10. Effective Date, Review and Amendment
These regulations are effective as of April 17th, 2008. The Board shall annually review these regulations and may make such amendments as it deems necessary and appropriate.